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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

KAM, CHIH MIN

ART UNIT PAPER NUMBER

1653

DATE MAILED: 01/14/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/813,775

Applicant(s)

DESAUVAGE ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-24,30 and 34-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-24,30 and 34-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3. 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group II, claims 16-24, 30 and 34-41, and SEQ ID NO:18 in Paper No. 13 is acknowledged. Regarding the examiner's requirement for election of one variant sequence of CHEPO, applicants traverse on the ground(s) that all variants listed in claims 34 and 35 are closely related to the CHEPO polypeptide of SEQ ID NO:2, and the selection of a specific sequence should be treated as an election of species requirement. The argument is not found persuasive because each peptide with different amino acid sequence has different chemical and physical properties, and would produce different effect, thus it is patentably distinct. Claims 1-15, 25-29, 31-33 and 42-44 have been canceled. Upon reviewing the sequence search on SEQ ID NO:18, it is found that SEQ ID NO:34 comprises SEQ ID NO:18, thus, claims 16-24, 30 and 34-41, along with only SEQ ID NOs: 2, 18 and 34 are rejoined and examined.

Claim Objections

2. Claim 20 is objected to because of the use "(I) hybridizing a test DNA....., (ii) culturing a host cell...., and (iii) recovering....". The numbering of the steps (i), (ii), and (iii) should be consistent.

3. Claims 30 and 34-41 are objected to because claims 30, 34 and 35 contain non-elected invention, and claims 36-41 depend from the claim containing non-elected sequences.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 19 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 19 is directed to a CHEPO polypeptide comprising the amino acid sequence of residue 1 or 28 to 193 of SEQ ID NO:2 or a fragment thereof sufficient to provide a binding site for an anti-CHEPO antibody. The specification indicates that the CHEPO fragments may be truncated at N- or C-terminus, or may lack internal residue as compared to the full length native protein, and the fragments share immunological activity with the native CHEPO polypeptide (page 43, paragraph 4; page 44, first paragraph). However, the specification does not specify which fragment reacts with an anti-CHEPO antibody, nor indicates how specific the reaction between the antibody and the polypeptide. There is no disclosure indicating the sequence of the fragment reacting with anti-CHEPO antibody specifically. Without guidance for structure to function/activity, one skilled in the art would not know which region of CHEPO is essential for immunological activity and how to identify a functional fragment. The lack of a structure to function/activity relationship and the lack of representative examples and teachings for the fragments which bind to anti-CHEPO antibody as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

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Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 16-24, 30 and 34-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
6. Claims 16-24, 30 and 34-41 are indefinite because of the use of the term "CHEPO". The term "CHEPO" renders the claim indefinite, it is unclear what the term stands for. A full spelled out word should be indicated at the first occurrence. Claims 17, 21, 23, 24 and 35-41 are included in the rejection because they are dependent on rejected claims and do not correct the deficiency of the claim from which they depend.
7. Claims 16, 17 and 21 are indefinite because of the use of the term "at least about 80% sequence identity". The term "at least about 80% sequence identity" renders the claim indefinite, it is unclear whether the sequence identity is greater than 80% as to "at least" or less than 80% as to "about". Claim 17 is included in the rejection because it is dependent on a rejected claim and does not correct the deficiency of the claim from which it depends.
8. Claim 18 is indefinite because of the use of the term "scoring at least 80% positives when compared to the sequence....". The term "scoring at least 80% positives when compared to the sequence...." renders the claim indefinite, it is unclear what the scores indicate, and what has been used to measure the scores.

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9. Claims 34 and 35 are indefinite as to "X" in the sequence, it is not clear what amino acid is used as "X" except that under 37 C.F.R. 1.821-1.825, X (Xaa) is "unknown" or "other" (see MPEP 2400, Table 3).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 16, 20 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Elliott *et al.* (WO 95/05465).

Elliott *et al.* discloses human erythropoitin isoforms and analogs having at least one additional site for glycosylation are prepared by expression of the DNA encoding the erythropoitin (page 5, lines 10-25; page 17, lines 3-6; Table 3-5; Example 6), and the sequence match indicates human erythropoitin has 99.3% sequence homology with SEQ ID NO:2 (see attached sequence match; claims 16, 20 and 21).

11. Claim 22 is rejected under 35 U.S.C. 103(a) as being anticipated by Hyttinen *et al.* (U. S. Patent 5,959,171).

Hyttinen *et al.* disclose a fusion protein, β -lactoglobulin-human erythropoitin is expressed in transgenic mice (Examples 2 and 3; claim 22). The amino acid sequence of human EPO is known in the art, which has 99.3% sequence homology with SEQ ID NO:2 (see sequence match), thus it is a CHEPO polypeptide.

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Conclusion

12. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*
Patent Examiner

January 10, 2003

Christopher S. F. Low
CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
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